DEPARTMENT OF H..LTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

APR 12 2001

WARNING LETTER

VIA FACSIMILE
VIA FEDERAL EXPRESS

Lonnie M. Smith
President and Chief Executive Officer
Intuitive Surgical, Incorporated
1340 West Middlefield Road
Mountain View, California 94043

Dear Mr. Smith:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has reviewed your web sites. The materials on these sites make misleading claims for Intuitive's da Vinci™ Surgical System (da Vinci™). The da Vinci™ is a device within the meaning of section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

In a February 20, 2001, letter we advised Intuitive that their belief the general clearance, for laparoscopic procedures, K990144, for the da Vinci™ system covered the use of the system in prostatectomy procedures was incorrect. That correspondence also identified irregularities in the company's web site and press releases.

Our review of your current web sites, which can be found at www.intusurg.com and www.intuitivesurgical.com, finds that Intuitive continues to promote the da Vinci™ off-label for prostatectomy procedures as well as cardiac procedures. Additionally Intuitive implies that the da Vinci™ system has use in a variety of applications that have not received agency clearance.

The indications for use stated in K990144 are as follows.

> The Intuitive Surgical™ Endoscopic Instrument Control System (herein referred to as the "da Vinci"™ System) is intended to assist in the accurate control of Intuitive Surgical™ endoscopic instruments including: rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories during laparaoscopic surgical procedures such as cholecystectomy or Nissen fundoplication. It is intended for use by trained physicians in an operating room environment.
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> Intuitive Surgical™ Instruments including scissors, scalpels, forceps/pickups, needle holders, clip appliers, and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

Intuitive's K002849 additionally allows for the use of the da Vinci™ in performing "general non-cardiovascular thoracoscopic surgical procedures such as internal mammary artery mobilization."

Examples of Intuitive's misleading promotion of cardiac procedures are found at www.intusurg.com/html/casestudies.html. Links to several case studies that describe cardiac procedures using the da Vinci™ are listed on this page. Those links follow.

Cardiac Surgery An Endoscopic Clinical Case Study: Double Vessel Beating Heart Bypass
Dresden Cardiovascular Institute, Germany

Cardiac Surgery An Endoscopic Clinical Case Study: Endoscopic Beating Heart CABG
Leipzig Heart Center, Germany

Cardiac Surgery An Endoscopic Clinical Case Study: Sequential Graft Bypass
Frankfurt University, Germany

Cardiac Surgery An Endoscopic Clinical Case Study: Coronary Artery Bypass Graft (TECAB)
Broussais Hospital, France

In addition to these case studies, on www.intusurg.com/html/clinfoot.html you also provide the clinical footage of a cardiac procedure (LIMA-LAD).

Your promotion of the cardiac procedures places Intuitive in violation of the agency's regulations at 21 C.F.R. 812.7(a) which prohibit the promotion of an investigational device until FDA has approved the device for commercial distribution and 21 C.F.R 812.7(d) which prohibits a sponsor from representing that an investigational device is safe and effective for the uses for which it is being investigated.

In addition to the promotion for cardiac procedures, Intuitive continues to promote the da Vinci™ for use in prostatectomies. At www.intuitivesurgical.com/html/news/news00g.html, there is a press release titled "World's First Totally Endoscopic, Computer-Enhanced Radical Prostatectomies." The press release discusses the use of the da Vinci™ while performing prostatectomies. Another page of your web site includes a section titled "Urology News" (www.intusurg.com/html/whatsnew.html) with a link to a case study titled, "Urology Surgery Radical Prostatectomy & Pelvic LA, An Endoscopic Clinical Case Study, Frankfurt University, Germany. At this link (www.intusurg.com/html/case5.html) you present a case study that includes graphic representations along with written descriptions of a prostatectomy procedure using the da Vinci™.

FDA's regulations at 21 CFR 801.4 provide that the intended use of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by circumstances surrounding the distribution of the article. This objective intent may be shown by, for example, labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

Intuitive's promotion of the device for off-label uses such as prostatectomies and cardiac procedures misbrands and adulterates the da Vinci™ system. The da Vinci™ is misbranded within the meaning of section 502(o) because no notice or other information respecting the device was submitted as required by section 510(k) of the Act. The uses for the device discussed in the above mentioned articles and case studies constitute major changes or modification to the intended use of the device. A major change or modification in the intended use requires the submission of premarket notification, as provided in the agency's regulations at 21 CFR 807.81(a)(3)(ii). The da Vinci™ system is adulterated within the meaning of section 501(f)(1)(B) because it is a class III device as defined by section 513(f) of the Act for which there is in effect neither an approved premarket approval application under section 515(a) of the Act nor an approved investigational device exemption under section 520(g) of the act.

Your device is further adulterated within the meaning of section 501(i) because it is a device for which an exemption has been granted under section 520(g) for investigational use and there has been a failure to comply with a requirement prescribed by or under such section.

This letter is not intended to be an all-inclusive list of deficiencies associated with your device. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may also be reflected in other promotional materials used by your firm. You are responsible for investigating and reviewing all materials to ensure compliance with applicable regulations.

Additionally your web page, titled, "Clinical Applications" at intusurg.com/html/clinicalapps.html, by its presentation, implies that the da Vinci™ system has broader uses than have been cleared by the agency. The following applications are listed : cardiac, general, gynecology, neuro surgery, orthopedic, pediatric, plastic surgery, spinal, thoracic, vascular and urology. We believe that your current clearance would not allow for general or specific promotional claims in a majority of these applications for the U.S. market.

You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil money penalties.

Please notify this office in writing, within 15 working days of your receipt of this letter, of the specific steps you have taken to correct the noted violations. Your response should include steps being taken to address any misleading information currently in the marketplace and to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Terri Garvin, Regulatory Counsel, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's San Francisco District. Please send a copy of your response to the District Director, 1431 Harbor Bay Parkway, Almeda, CA 94502-7070.

Sincerely yours,

Byron Taft

for Larry Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health